K091749

Kimberly-Clark Corporation

Traditional 510(k) for Kimberly-Clark* U by KOTEX Click*
Unscented Menstrual Tampons

Section 5. 510(k) SUMMARY

DEC 23 2009

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Submitter's Name:	Kimberly-Clark Corporation
Submitter's Address:	2100 Winchester Road Neenah, WI 54956 **Mailing address for regulatory correspondence:** 1400 Holcomb Bridge Road Roswell, GA 30076-2199
Submitter's Phone No:	770-587-7131
Submitter's Fax No.	920-380-6308
Date of Preparation:	June 1, 2009
Name of Device Trade Name: Common Name: Classification Name: Product Code:	 U by KOTEX Click* Unscented Menstrual Tampons; Regular, Super and Super Plus absorbencies Menstrual Tampon, Unscented Tampon, Menstrual, Unscented HEB
Legally marketed device to which equivalency is claimed:	Kimberly-Clark* KOTEX® Security® Tampons – K864750
Description of the device:	This device is a conventional unscented menstrual tampon consisting of an absorbent pleget, a withdrawal cord and an applicator. The absorbent pledget consists of a ribbon of rayon fibers. A viscose-polyester blend withdrawal cord is placed on the ribbon and the ribbon is radially wound, then compressed into a traditional eight-groove bullet-shaped pledget, overwrapped with a non-woven fabric. The formed pledget is inserted into a three-piece plastic applicator consisting of an inner plunger tube, a clear middle telescopic tube and an outer insertion tube (barrel) formed with a closed, rounded tip. Each tampon is wrapped in an individual plastic film wrapper and packaged in sealed multi-unit containers for retail sale.

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
(Continued)

Summary of technological characteristics compared to the predicate device:	The device is similar to the predicate device in terms of component materials, overall design, packaging and labeling. This device differs from the predicate device in the exact design and composition of its pledget, i.e. 100% rayon radially-wound eight-groove bullet-shaped pledget as compared to a rectangular pad consisting of a 70/30 cotton/rayon blend compressed into a bullet shape. Color of the subject device and predicate applicators are also different. The subject device is composed of a three piece telescoping plastic applicator in lime green, pink, blue and yellow pearlescent colors whereas the predicate device consists of a two-piece lavender pearlescent plastic applicator.		
Brief description of preclinical toxicology: (biocompatibility) tests	**Preclinical Tests**	**Standard**	**Performance**
	Genotoxicity Test (MLA)	ISO 10993, Part 3	Meets
	Genotoxicity Test (AMES)	ISO 10993, Part 3	Meets
	Genotoxicity Test (Mouse Micronucleus)	ISO 10993, Part 3	Meets
	Cytotoxicity Test	ISO 10993, Part 5	Meets
	Mucosal Irritation Test	ISO 10993, Part 10	Meets
	Mucosal Sensitization Test	ISO 10993, Part 10	Meets
Safety Assessment:	The subject 510(k) device has undergone an extensive series of safety tests, including an assessment of performance characteristics, preclinical microbiological testing and biocompatibility testing. The results of these studies support the conclusion that the subject 510(k) device is equivalent and as safe as the predicate device, the Kimberly-Clark* KOTEX® Security® Tampon.		
Effectiveness:	Kimberly-Clark* U by KOTEX Click* Unscented Menstrual Tampons comply with the syngyna absorbency requirements of 21 CFR § 801.430 as does the predicate device, the Kimberly-Clark* KOTEX® Security® Tampons.		
Conclusions:	The results of the extensive performance assessments, *in vitro* microbiological and biocompatibility testing of the subject device, Kimberly-Clark* U by KOTEX Click* Unscented Menstrual Tampons, support the conclusion that it is safe for its intended use and that it is substantially equivalent to the predicate device, the Kimberly-Clark* KOTEX® Security® Tampon.		

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Cheryl M. Sanzare
Associate Director Global Regulatory Affairs
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
ROSWELL GA 30076

DEC 23 2009

Re: K091749
Trade/Device Name: U By Kotex® Click™ Menstrual Tampon (Unscented)
Regulation Number: 21 CFR §884.5470
Regulation Name: Menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: December 11, 2009
Received: December 14, 2009

Dear Ms. Sanzare:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K091749

Kimberly-Clark Corporation

INDICATIONS FOR USE

Applicant: **Kimberly-Clark Corporation**

510(k) Number: K091749

Device Name: Kimberly-Clark* U by KOTEX Click* Unscented Menstrual Tampons

Indications for Use: Kimberly-Clark* U by KOTEX® Click* is an unscented menstrual tampon inserted into the vagina to absorb menstrual fluid.

Prescription Use_____ OR Over-The-Counter ___X___
Per 21CFR 801.109 Subpart D Per 21CFR 801.109 Subpart C

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091749